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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,408	08/05/2003	Jong-Gu Park	57354-08USA	8424
7590	07/21/2006		EXAMINER	
JHK Law P.O. Box 1078 La Canada, CA 91012-1078			KELLY, ROBERT M	
			ART UNIT	PAPER NUMBER
			1633	
DATE MAILED: 07/21/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/634,408

Applicant(s)

PARK ET AL.

Examiner

Robert M. Kelly

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's argument and amendment of 5/30/06 are entered.

Claims 1-20 remain pending and are considered.

Note: Claim Amendments

Applicant's response contained a list of claims, however, the claims did not contain any claim identifiers, nor did it contain any markings of amendments. However, the Examiner notes that not claims appear to have been amended, and, in light of the discretion permitted by the Office of claim identifier language, the claims have been entered. However, future amendments will be responded to with a notice of non-compliant amendment, should Applicant incorrectly submit such claim amendments.

Claim Rejections - 35 USC § 112 - enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-20 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, for reasons of record. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Response to Argument - enablement

Applicant's argument of 5/30/06 has been fully considered but is not found persuasive.

Applicant argues that they used FGS-Kist mice, which develop nephritis, and showed that the administration of certain cytokines into kidney of cells of these animals results in significantly reduced nephritis (Applicant's argument of 5/30/06, p. 5, paragraph 4).

Such is not persuasive. Applicant has not shown "significant reduction of nephritis" for the mice used, but, as has been stated, at best, a delay in the onset of nephritis, when the specific vector is directly administered prior to the onset of nephritis. Such does not amount to reducing inflammation, treating nephritis, preventing nephritis, or reducing the excretion of polypeptides in urine, for any subject, for any of the transgenes, and for any of the disorders encompassed. (Official Action of 11/21/05, e.g., pp. 12-13.)

Applicant argues that the model is an art-accepted model, and the Examiner has failed to provide evidence why the results do not correlate with the treatment of nephritis in humans (pp. 5-6, paragraph bridging).

Such is not persuasive. Applicant's model may be art accepted in terms of a model which is used in the art, but such model is not art-accepted in terms of predicting treatment in any animal (Official Action of 11/21/05, pp. 9 and 12). In fact, Applicant's own non-patent literature describes how even Applicant does not reasonably predict such treatments for the breadth claimed (Official Action of 11/12/05, p. 12, and Choi, et al. (2003) Gene Therapy, 10: 559-68, e.g., p. 565, paragraph bridging columns). Furthermore, Applicant has failed to address any other issue in the prior Official Action, e.g., issues with the limits of delivery and expression in certain cell types related to the type of vector, and particular classes of genes claimed which actually are predicted to exacerbate inflammation in kidney conditions (p. 9). Further, at best, even if Applicant's model was art-accepted, Applicant's tests and the model itself would only

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indicate influences on disease progression in a particular kidney condition, but certainly not the breadth of what is claimed. Hence, Applicant's claims bear no correlation to what can be reasonably predicted, as has been explained throughout the Official Action of 11/12/05.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Kelly, Art Unit 1633, whose telephone number is (571) 272-0729. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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